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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,677	01/07/2005	Akira Yanagawa	264232US0PCT	9965

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
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ALEXANDRIA, VA 22314

EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/519,677

Applicant(s)

YANAGAWA, AKIRA

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 11-22 are pending. Applicant cancelled claims 1-10 (i.e. all the original claims). Claims 21-22 are withdrawn from consideration as being directed to a non-elected invention. **Claims 11-20 are under consideration in the instant office action.** Receipt and consideration of Applicant's amended claim set and remarks/arguments submitted on November 8, 2006 is acknowledged.

Moot Rejections/objections

All rejections and/or objections of claims 1-10 cited in the previous office action mailed on June 15, 2006 **are moot**, because said claims have been cancelled.

Election/Restrictions

Newly submitted claims 21-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the cited claims claim a method of preparing a composition for nasal absorption, which was not present in the previously examined claim set. A "use claim" is not equivalent to a claim drawn to a method of making.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The objection to the abstract because it consists of more than one paragraph is maintained for the reasons of record set forth on page 2 of the previous office action mailed on June 15, 2006. An amended abstract was not received with Applicants' response dated November 8, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1616

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa (U.S. Patent No. 5,603,943) ("USPN '943"), as evidenced by the 1994-1995 Drug Information Handbook ("DIH"), as set forth on pages 4-7 of the office action mailed on June 15, 2006.

Response to Arguments

Applicant's arguments filed November 8, 2006 have been fully considered but they are not persuasive. Applicant's traversal of the instant rejection is based on their assertion that (1) the prior art does not teach that calcium carbonate as a carrier advantageously produces little stimulation of the nasal mucosa; (2) USPN '943 teaches a large number of possible carriers and therefor lacks a teaching suggesting the superior properties of associated with calcium carbonate; and (3) Applicant's amendment removing analgesics devoid of sedating activity has obviated this rejection.

The Examiner respectfully disagrees. Concerning argument (3), contrary to Applicant's assertion, not all opiates known to exhibit sedating effects have been removed from the claims (i.e. morphine, buprenorphine, and salts thereof). Furthermore, it is noted that Yanagawa specifically teaches that any active agent having a molecular weight not more than 40,000 and this genus thus encompasses all the opiates disclosed in Applicant's specification. Therefore, it

Art Unit: 1616

would have been obvious to a person of ordinary skill in the art to utilize opiates or any active substance having a molecular weight below 40,000 in Yanagawa's claimed nasal composition.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., carrier advantageously produces little stimulation of the nasal mucosa) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Notwithstanding the fact that the property of having little stimulation of the nasal mucosa is not a currently claimed limitation, even if it were present it would not impart patentability to the claimed composition, because this is a property of the carrier and the prior art teaches the same carrier.

The selection of calcium phosphate or calcium carbonate as the carrier is obvious because the prior art teaches that these are suitable carriers (see for example claims 4 and 9). Hydroxyapatite is a naturally occurring calcium phosphate mineral. An ordinary skilled artisan would have been motivated to select calcium carbonate or calcium phosphate as the carrier material, because these are carriers specifically cited in the claims of an issued U.S. patent drawn to nasally administrable compositions. As a result, an ordinary skilled artisan would have had a reasonable expectation of success upon selection of these calcium compounds as a carrier in nasally administrable compositions. The combination of two or more suitable carrier materials would have been obvious because in Example 7 (col. 12, line 41 through col. 13, line 20) Yanagawa teaches a composition made from the combination of two suitable carrier materials. Because both calcium carbonate and calcium phosphate are taught and claimed by Yanagawa as

Art Unit: 1616

suitable carrier materials in a nasally administrable composition, an ordinary skilled artisan would have been motivated to select this combination and would have had a reasonable expectation of success when using this combination in a nasally administrable composition. Regarding the amounts of carrier and active in Applicants' claimed composition (i.e. claim 15), Yanagawa teaches carrier amounts ranging from 70% to approximately 99.995%, with respect to the total weight of the composition (i.e. w/w), in col. 7, lines 48-57. Using arithmetic and the amount of carrier taught by Yanagawa, an ordinary skilled artisan would deduce that a suitable amount of active in Yanagawa's compositions would range from approximately 0.005 % w/w to 30% w/w. The amount of carrier and active claimed by Applicant overlaps with the ranges of the amounts of carrier and active taught by Yanagawa.

Regarding the treatment of pain, it is known in the art that opiates are both sedatives and analgesics. See the Drug Information Handbook, Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 1066, which was cited on page 6 of the office action mailed on June 15, 2006. It would have been obvious to a person of ordinary skill in the art that one could use an analgesic to treat all kinds of pain, such as pain attributed to terminal cancer or cancer of the digestive system.

For the reasons articulated above and already of record, the Examiner concludes that an ordinary skilled artisan would have found claims 1-11 *prima facie* obvious over the teachings of Yanagawa because Yanagawa teaches nasally administrable compositions using the same carrier materials, in similar amounts, and that any active substance having a molecular weight below 40,000 is suitable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-20 are rejected as being unpatentable over claims 1-2, 4, and 9-14 of U.S.

Patent No. 5,603,943 (USPN ‘943) as evidenced by the 1994-1995 Drug Information Handbook (“DIH”) for the reasons of record set forth on pages 7-8 of the office action mailed on June 15, 2006. It is noted that the obviousness-type double patenting rejection of claims 1-10 cited as being unpatentable over claims 1-2, 4, and 9-14 of U.S. Patent No. 5,603,943 (USPN ‘943) on pages 7-8 of the office action mailed on June 15, 2006 was not specifically addressed in Applicant’s response.

Conclusion

Claims 11-20 are rejected. Claims 21-22 are withdrawn from consideration. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

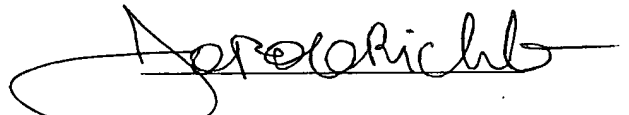
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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